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09/964,858	09/28/2001	Margaret K. Hostetter	P07274US02/BAS	2374

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ALEXANDRIA, VA 22314

EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/25/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/964,858

**Applicant(s)**

HOSTETTER ET AL.

**Examiner**

S. Devi, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11,14,16 and 18-30 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 5-8,16,18-22 and 24-30 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,3,4,9,11,14 and 23 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

1) Acknowledgment is made of Applicants' amendment filed 09/09/03 (paper no. 6) in response to the non-final Office Action mailed 05/07/03 (paper no. 11). With these, Applicants have amended the specification, and have submitted a corrected drawing sheet.

### **Status of Claims**

2) Claim 2, 10, 12, 13, 15 and 17 have been canceled via the amendment filed 09/09/03.  
Claims 1, 3, 4, 9, 11, 14 and 23 have been amended via the amendment filed 09/09/03.  
Claims 1, 3-9, 11, 14, 16 and 18-30 are pending in this application.  
Claims 1, 3, 4, 9, 11, 14 and 23 are under examination.

### **Prior Citation of Title 35 Sections**

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

5) The objection to the specification made in paragraph 9(a) of the Office Action mailed 05/07/03 (paper no. 11) is withdrawn in light of Applicants' amendments to the specification.  
6) The objection to the specification made in paragraph 9(b) of the Office Action mailed 05/07/03 (paper no. 11) is withdrawn in light of Applicants' amendments to the specification and/or the drawing.

### **Rejection(s) Moot**

7) The provisional rejection of claims 2, 12, 13, 15 and 17 made in paragraph 11 of the Office Action mailed 05/07/03 (paper no. 11) under the judicially created doctrine of obviousness-type double patenting, is moot in light of Applicants' cancellation of the claims.  
8) The rejection of claim 10 made in paragraph 12 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is

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moot in light of Applicants' cancellation of the claim.

9) The rejection of claims 2 and 13 made in paragraph 13(a) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 10 made in paragraph 13(b) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 2 made in paragraph 13(c) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

12) The rejection of claims 15 and 17 made in paragraph 13(f) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

13) The rejection of claims 2, 12, 13 and 15 made in paragraph 15 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 102(b) as being anticipated by Hostetter *et al.* (US 5,886,151 - Applicants' IDS) ('151), is moot in light of Applicants' cancellation of the claims.

14) The rejection of claim 10 made in paragraph 18 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 103(a) as being unpatentable over Hostetter *et al.* (US 5,886,151 - Applicants' IDS) ('151), is moot in light of Applicants' cancellation of the claim.

15) The rejection of claims 12 and 17 made in paragraph 19 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 103(a) as being unpatentable over Hostetter *et al.* (US 5,886,151 - Applicants' IDS) ('151), is moot in light of Applicants' cancellation of the claims.

#### **Rejection(s) Withdrawn**

16) The rejection of claim 9 made in paragraph 12 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendments to the claim.

17) The rejection of claim 3 made in paragraph 13(a) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.

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18) The rejection of claims 4 and 11 made in paragraph 13(d) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

19) The rejection of claim 9 made in paragraph 13(e) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claim 23 made in paragraph 13(a) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

21) The rejection of claim 1 made in paragraph 16 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 102(b) as being anticipated by White *et al.* (*J. Cell Biochem. Suppl.* 0, page 173, 1990), or Hostetter *et al.* (*J. Cell Biochem. Suppl.* 16F: page 149, x110, 1991), withdrawn in light of Applicants' amendment to the claim.

#### **Rejection(s) Maintained**

22) The rejection of claim 14 made in paragraph 13(a) of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

23) The provisional rejection of claims 1, 3, 4, 14 and 23 made in paragraph 11 of the Office Action mailed 05/07/03 (paper no. 11) under the judicially created doctrine of obviousness-type double patenting over claims 28, 29, 40-42, 45, 46 and 48 of the co-pending application 09/978,343, is maintained for reasons set forth therein and herebelow. The new claim 60 of the co-pending application is now included in the rejection statement.

24) The rejection of claims 1, 3, 4, 13 and 14 made in paragraph 15 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 102(b) as being anticipated by Hostetter *et al.* (US 5,886,151 - Applicants' IDS) ('151), is maintained for reasons set forth therein and herebelow.

25) The rejection of claims 1 and 9 made in paragraph 18 of the Office Action mailed 05/07/03 (paper no. 11) under 35 U.S.C. § 103(a) as being unpatentable over Hostetter *et al.* (US 5,886,151 - Applicants' IDS) ('151), is maintained for reasons set forth therein and herebelow.

26) The rejection of claims 1 and 11 made in paragraph 19 of the Office Action mailed 05/07/03

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(paper no. 11) under 35 U.S.C. § 103(a) as being unpatentable over Hostetter *et al.* (US 5,886,151 - Applicants' IDS) ('151), is maintained for reasons set forth therein and herebelow.

With regard to the teachings of Hostetter *et al.* ('151 and 09/978,343), Applicants contend that these documents do not disclose or suggest the propeptide region of claim 1, much less any antibodies that bind thereto. Applicants state that the instantly claimed antibodies have been shown to prevent cleavage of the propeptide. Applicants submit that the prior works that formed the basis of the two applied documents did not recognize that there was such a propeptide region at the specific location of amino acids 1-263 of the Int1p protein, much less that the cleavage of this region was an important factor in *Candida* virulence. Applicants state that these references do not appreciate the problem of virulence activation and thus cannot relate at all to the creation of antibodies that recognize this specific region and act to prevent such cleavage. Applicants further contend that Hostetter *et al.* ('151 and 09/978,343) do not disclose or suggest the present claims wherein an antibody can bind specifically to the propeptide region so as to prevent the activation and virulence of *Candida* yeast. Applicants argue that the prior art antibodies to the whole Int1p protein are irrelevant to the specific claimed invention which relates to antibodies that can bind to the specific propeptide region, since antibodies to a whole protein will not have the same properties as antibodies which can target and bind to a specific region, and prevent propeptide cleavage. Applicants urge that the prior art documents do not disclose or suggest the claimed antibody which can bind specifically to the Int1p region.

Applicants' arguments have been carefully considered, but are non-persuasive. Instant claims are not directed to a method of virulence activation in *Candida albicans*, or to a method of preventing the activation and virulence of *Candida*. Instead, the claims are drawn to an isolated antibody specific to a region of the Int1p protein of *Candida albicans*. Hostetter's ('151 and 09/978,343) antibodies are to the Int1p protein of *Candida albicans* and fragments or peptides thereof, the amino acid sequence of which Int1p protein comprises the instantly claimed 1-263 amino acids of SEQ ID NO: 1, or amino acid residues 218-263 of the instantly recited SEQ ID NO: 1. See the sequence search reports attached to the Office Action mailed 05/07/03. Hostetter's antibodies block the adhesion of *Candida albicans* to epithelial cells. It was well known in the art that conventional antisera, such as, Hostetter's antisera are heterogeneous and contain numerous

antibody populations with specificity to the various antigenic determinants expressed on the immunogen. The conventional antisera represent a mixture of specificities and show wide variation in antibody specificity and antibody reactivity (see paragraph bridging pages 159 and 161 of Nakamura RM. *Clin. Physiol. Biochem.* 1: 160-172, 1983). Therefore, Hostetter's ('151 and 09/978,343) antisera are reasonably expected to contain at least one antibody specific to the 1-263 residue-containing portion of the Int1p protein of *Candida albicans* (the amino acid sequence of SEQ ID NO: 1). Given the presence of 1-263 amino acid residues, or amino acid residues 218-263 in the prior art Int1p protein of *Candida albicans*, or fragments or peptides thereof, as demonstrated by the sequence search reports attached to the Office Action mailed 05/07/03, Hostetter's ('151 and 09/978,343) antisera are reasonably expected to contain at least one antibody with the capacity to bind to the 1-263 residue-containing or 218-263 residue-containing portion of the Int1p protein of *Candida albicans*. Although Hostetter's documents do not refer to the amino acid residues 1-263 of the Int1p protein of *Candida albicans* as the 'propeptide', the exact structural or amino acid composition that constitutes the 'propeptide' is contained in the prior art protein, or a fragment or peptide thereof. Because of the 100% structural identity in the amino acid composition between the instantly recited amino acid sequence and the prior art amino acid sequence, the capability to prevent the cleaving of the propeptide as recited in claim 3, is viewed as an inherent functional property inseparable from the prior art antibody. The rejection stands.

#### **New Rejection(s)**

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims.

#### **Rejection(s) under 35 U.S.C § 112, Second Paragraph**

27) Claims 1, 3, 4, 9, 11, 14 and 23 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1, as amended, includes the confusing and/or redundant limitation: 'the amino acid sequence of amino acids 1-263 of SEQ ID NO: 1'. In order to distinctly claim the subject matter and for clarity, it is suggested that Applicants replace the recitation with --amino acid residues 1-263 of the amino acid sequence of SEQ ID NO: 1--.

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(b) Claims 3 and 14, as amended, are improper because of their redundant and/or identical scope.

(c) Claims 3, 9, 11, 14 and 23, which depend from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Claim 76 is confusing, and it does not further limit claim 47, since both claims cover a polypeptide comprising at least fifteen contiguous amino acids of SEQ ID NO: 5.

#### Remarks

28) Claims 1, 3, 4, 9, 11, 14 and 23 stand rejected.

29) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

30) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

31) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.




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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November, 2003

  
S. DEVI, PH.D.  
PRIMARY EXAMINER